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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,822	01/13/2005	Mitsuru Horiba	ADACHI P265US	9877

20210 7590 03/18/2008
DAVIS BUJOLD & Daniels, P.L.L.C.
112 PLEASANT STREET
CONCORD, NH 03301

EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,822	Applicant(s) HORIBA ET AL.	
	Examiner Shefali D. Patel	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004 and 05 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/20/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because the abstract is 169 words long:

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.** The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The title of the invention is not descriptive as it is simply "Catheter", which is very broad in scope. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

3. Claim 6 is objected to because of the following informalities:

In regards to claim 6, change "**fist** handling portion" to "**first** handling portion".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5,921,993), in view of Townsend (US 6,066,102).

In regards to claim 6, Yoon teaches an instrument [416] (Figures 29-31) used by being inserted from outside of a body into a coelem (Abstract) and reaching a distal end thereof to a target region while a proximate end thereof being remained outside of the body (Figure 20).

Though Figure 20 shows the use of another embodiment of the instrument [216], the preferred embodiment of the instrument [416] is intended to be inserted into the body in the same way with the proximate end of the instrument outside of the body and the distal end of the instrument inside of the body, since instrument [416] is simply a modification of instrument [216] (column 24, lines 39-47). Said instrument [416] comprises:

- a. a forceps mechanism having a first handling portion (handle [440]) at the proximate end and a grasping portion (grasping members [450A][450B]) at the distal end, the grasping portion being configured to open and close in conjunction with manipulation at the first handling portion (column 25, lines 2-7), and being capable of holding the target region (Abstract, “*grasping an anatomical tubular structure at the internal operative site with a grasping member of the instrument...*”)
- b. an injection mechanism having a second handling portion (hand grip [421]) at the proximate end, and an injection needle (needle [404]) at the distal end, the injection needle being configured to be moved forward up to a position to be protruded from the distal end, and to be moved back up to a position to be stored inside of the distal end

(column 25, lines 20-27), the injection mechanism being capable of puncturing the target region with the injection needle (column 25, lines 52-54) and injecting injectant into the target region (column 25, lines 54-56)

Yoon does not state that the instrument [416] is a catheter; however, a catheter is defined as a tubular medical device for insertion into canals, vessels, passageways, or body cavities, usually to permit injection or withdrawal of fluids or to keep a passage open. Since the instrument of Yoon is a tubular medical device that is inserted into a body cavity and the instrument has a needle to inject fluid into the body cavity, Yoon indirectly teaches that said instrument is a catheter. Yoon does not teach that the forceps mechanism has a link mechanism configured to open and close the grasping portion corresponding shifting of the grasping portion. Townsend et al teaches a biopsy device (Figure 11) having a forceps mechanism [28] with a link mechanism (link coupling [297] with links [296][298]) configured to open and close the grasping portion (first jaw [306] and second jaw [308]) corresponding shifting of the grasping portion (column 12, lines 38-45). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism of Yoon to incorporate the link mechanism, as taught by Townsend et al, in a modified device of Yoon and Townsend et al, as the links [296][298] will function to minimize stress upon the grasping portion, which in turn will minimize stress felt by the patient, since the grasping portion will grasp and hold a target region of the patient's body.

In regards to claim 8, Yoon teaches that the forceps mechanism (Figures 29-31) comprises a lock device (locking mechanism [447]) that forbids the grasping portion [450A][450B] opening and closing (column 25, lines 5-9).

In regards to claim 10, Yoon teaches that the injection mechanism (Figures 29-31) comprises a lock device (locking mechanism [447']) that forbids the injection needle moving back (column 25, lines 30-36).

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5,921,993) and Townsend et al, as applied to claim 6 above, and further in view of Yoon (US 5,665,100).

In regards to claim 7, Yoon ('993) does not teach a spring biasing the grasping portion of the forceps mechanism to a closed configuration, since Yoon ('993) teaches that the grasping portion [450A][450B] is made of resilient, flexible, or spring materials, or materials having shape memory, to be resiliently biased toward an open configuration while being movable to a closed configuration and back to the open configuration (column 8, lines 49-57). Yoon ('100) teaches an endoscope instrument with a forceps mechanism (Figures 2-3, forceps unit [11]) that is configured to bias a grasping portion (jaws [18][20]) to a direction to close the grasping portion with the force of a spring (helical coil spring bias member [53]) (column 7, lines 14-28). Based on the teachings of Yoon ('100), it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a spring to the forceps mechanism of Yoon ('993), in a modified device of Yoon ('993), Townsend et al, and Yoon

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(‘100), as biasing the grasping portion to a closed configuration, at the beginning of the medical procedure, will ensure a smooth entry of the catheter into the body without inadvertent snagging of anatomical tissue, which may occur if the grasping portion is in an open configuration (column 2, lines 30-33).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5,921,993) and Townsend et al, as applied to claim 6 above, and further in view of Yoon (US 3,870,048).

In regards to claim 9, Yoon (‘993) does not teach a spring biasing the injection needle to move in a backwards direction into the injection mechanism, as Yoon (‘993) only teaches that the extent that the second handling portion [421] is squeezed or compressed controls the extension or retraction of the needle [404] (column 25, lines 23-32). Yoon (‘048) teaches a needle instrument (Figures 15-16) with an injection mechanism configured to bias an injection needle (hollow rod [46] with hole [47]) (column 5, lines 42-51). Based on the teachings of Yoon (‘048), it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a spring to the injection mechanism of Yoon (‘993), in a modified device of Yoon (‘993), Townsend et al, and Yoon (‘048), as biasing the needle to a retracted configuration, at the beginning of the medical procedure, will ensure a smooth entry of the catheter into the body without an inadvertent needle stick to the user or to an incorrect target site of the patient’s body.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Takayama et al (JP 05-184535).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shefali D. Patel whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
03/11/2008
/Kevin C. Sirmons/

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Supervisory Patent Examiner, Art Unit 3767